Application No.: 10/542,435 Filed: May 2, 2006

Page 8

Attorney Docket No.: JHU2090-1

REMARKS

In the present communication, claims 2 and 9 have been amended; claims 3, 4, 7 and 13 have been canceled; and no claims have been added. The amendments add no new matter and are fully supported by the specification and claims as filed. Upon entry of the present amendment, claims 2, 9-10 and 19 will be pending in this application.

Rejections under 35 U.S.C §102

Applicants respectfully traverse the rejection of claims 2, 4, 7, 9-10, 13 and 19 under 35 U.S.C. §102(b), as allegedly anticipated by Lin et al. (*Nature*, 410: 84-88 (March 1, 2001)). Claims 4, 7 and 13 have been canceled rendering the rejection moot as to such claims.

To anticipate, a single reference must inherently or expressly teach each and every element of the claimed invention. *In re Spada*, 15 USPQ2d 1655 (Fed Cir. 1990); and *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP § 2131.

Specifically, the Office Action alleges, that Lin et al. teach each of the active steps of the claimed method including contacting a neuronal cell with a test compound and assaying the ability of the test compound to modulate the expression of GTRAP3-18 protein expression and activity as determined by glutamate transport (EAAC1) activity.

Without acquiescing to the rationale presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended claim 2 to recite a method for identifying a compound which modulates cellular glycosylation in which the test compound is identified by assaying the ability of the compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide by detecting the level of glycosylation of a GTRAP3-18 target molecule. Support for the amendment may be found throughout the specification, for example on page 13, lines 18-21 and Figures 5 and 6, as well as in canceled claim 3. Applicants submit that Lin et al. fail to teach a method for identifying a compound including assaying the ability of the compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide by detecting the level of glycosylation of a GTRAP3-18 target molecule.

Application No.: 10/542,435

Filed: May 2, 2006

Page 9

Attorney Docket No.: JHU2090-1

Accordingly, withdrawal of the rejection under 35 U.S.C. §102(b) is respectfully requested.

Applicants respectfully traverse the rejection of claims 2, 4, 7, 9, 13 and 19 under 35 U.S.C. §102(e), as allegedly anticipated by U.S. Patent No. 6,808,893 (Rothstein et al.). Claims 4, 7 and 13 have been canceled rendering the rejection moot as to such claims.

Specifically, the Office Action alleges, that Rothstein et al. teach each of the active steps of the claimed method including contacting a neuronal cell with a test compound and assaying the ability of the test compound to modulate the expression of GTRAP3-18 protein expression.

Without acquiescing to the rationale presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended claim 2 to recite a method for identifying a compound which modulates cellular glycosylation in which the test compound is identified by assaying the ability of the compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide by detecting the level of glycosylation of a GTRAP3-18 target molecule. Applicants submit that Rothstein et al. fail to teach a method for identifying a compound including assaying the ability of the compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide by detecting the level of glycosylation of a GTRAP3-18 target molecule.

Accordingly, withdrawal of the rejection under 35 U.S.C. §102(e) is respectfully requested.

Rejections under 35 U.S.C §103(a)

Applicants respectfully traverse the rejection of claims 3 and 13 under 35 U.S.C. §103(a), as allegedly obvious over Lin et al. as applied to claims 2, 4, 7, 9-10 and 13, and further in view of Hirabayashi et al. (*Journal of Chromatography B*, 771: 67-87 (May 5, 2002)). Claims 3 and 13 have been canceled rendering the rejection moot as to such claim. As the rejection may be applied to the pending claims Applicants present the following arguments.

The recent U.S. Supreme Court decision in KSR International v. Teleflex Inc. (82 USPQ 2d 1385), modified the standard for establishing a prima facie case of obviousness. Under the KSR rule,

Application No.: 10/542,435 Filed: May 2, 2006

Page 10

Attorney Docket No.: JHU2090-1

three basic criteria are considered. First, some suggestion or motivation to modify a reference or to combine the teachings of multiple references still has to be shown. Second, the combination has to suggest a reasonable expectation of success. Third, the prior art reference or combination has to teach or suggest all of the recited claim limitations. Factors such as the general state of the art and common sense may be considered when determining the feasibility of modifying and/or combining references.

As discussed above, without acquiescing to the rationale presented in the Office Action, and in order to expedite prosecution of the instant application, Applicants have amended claim 2, by incorporating the limitation of canceled claim 3. As amended, claim 2 recites a method for identifying a compound which modulates cellular glycosylation in which the test compound is identified by assaying the ability of the compound to modulate the expression of a GTRAP3-18 nucleic acid molecule or polypeptide, or the activity of a GTRAP3-18 polypeptide by detecting the level of glycosylation of a GTRAP3-18 target molecule.

The Examiner alleges that Lin et al. teach a method including contacting cells expressing GTRAP3-18 with test compounds and assaying the effects of the test compound on both GTRAP3-18 protein expression and GTRAP3-18 activity via association with the co-expressed excitatory amino acid transporter EAAC1. However, the Office Action acknowledges that Lin et al. fail to teach determining the ability of a test compound to modulate GTRAP3-18 by detecting the level of glycosylation of a GTRAP3-18 target molecule.

Applicants submit that the Office Action fails to establish a *prima facie* case of obviousness because the cited references fail to provide some suggestion or motivation to modify a reference or combine the teachings of the reference to arrive at the claimed invention. As discussed above, Lin et al. fail to provide a method of identifying a modulator of cellular glycosylation associated with the GTRAP3-18 glycosylation pathway as claimed. Further, Lin et al. fail to teach or suggest a correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation as claimed. Similarly, Hirabayashi et al. also fail to remedy the deficiency since the reference fails to teach or suggest such a correlation. Accordingly, one of skill in the art would not be motivated to assay the ability of GTRAP3-18 to modulate glycosylation of glutamate transporter

In re Application of
Rothstein and Ruggiero
Application No.: 10/542,435

Filed: May 2, 2006

Page 11

PATENT Attorney Docket No.: JHU2090-1

proteins. The Office Action asserts that the skilled artisan would be motivated to combine the references since Hirabayashi et al. allegedly teach that quantification of glycosylation allows for a fuller investigation of cellular function. However, Hirabayashi et al. fail to teach or suggest identifying specific modulators of cellular glycosylation or any specific proteins involved in cellular glycosylation, such as GTRAP3-18. Accordingly, one of skill in the art would not be motivated to determine glycosylation of proteins specifically in the GTRAP3-18 pathway.

Applicants submit that even if one were to combine the teachings of Lin et al. and Hirabayashi et al., the resulting combination would not be *prima facie* obvious over the claimed invention since the combined teachings fail to disclose each and every claim limitation. As discussed above, Applicants respectfully submit that both Lin et al. and Hirabayashi et al. fail to provide a method of identifying a modulator of cellular glycosylation associated with the GTRAP3-18 glycosylation pathway as claimed. Further, Applicants respectfully submit that both Lin et al. and Hirabayashi et al. are silent with respect to the correlation between GTRAP3-18 activity regulation or expression and modulation of cellular glycosylation.

Accordingly, withdrawal of the rejection under 35 U.S.C. §103(a) is respectfully requested.

Application No.: 10/542,435

Filed: May 2, 2006

Page 12

Conclusion

In view of the amendments and above remarks, it is submitted that the claims are in condition for allowance, and a notice to that effect is respectfully requested. The Examiner is invited to contact Applicants' undersigned representative if there are any questions relating to this application.

The Commissioner is hereby authorized to charge the total amount of \$960.00 to Deposit Account No. 07-1896. A payment of \$555.00 for the Petition for Three-Month Extension of Time fee (small entity) and a payment of \$405.00 for the Request for Continued Examination fee. No other fees are deemed necessary with the filing of this paper. However, if any additional fees are due, the Commissioner is further authorized to charge any fees, or make any credits, to Deposit Account No. 07-1896 referencing the above-identified attorney docket number.

Respectfully submitted,

PATENT

Attorney Docket No.: JHU2090-1

Date: August 7, 2009

Matthew J. Herholzer, J.D. Registration No. 53,021

Telephone: (858) 638-6638 Facsimile: (858) 677-1465

DLA Piper LLP (US) 4365 Executive Drive, Suite 1100 San Diego, CA 92121-2133 USPTO Customer Number 28213